REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-14 are now pending in this application. Claim 1 as amended is a combination of original claims 1 and 4. Claim 4 as amended and new claim 13 reintroduce the second ranges from claims 2 and 3 respectively. New claims 14 provides a further embodiment of the invention. The remaining amendments are addressed below. No new matter has been added by this amendment.

The applicants inadvertently omitted the foreign references cited in the previous IDS and a new IDS is being submitted concurrently with this response.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE 35 U.S.C 101 REJECTION HAS BEEN OVERCOME

Claims 10-12 were rejected for reciting a use with out setting out any steps involved in the process. In response, the applicants have amended claims 10-12 from the "Swiss-style" method of use format to an alternative method of use format which places the claims in better compliance with U.S. practice.

With regard to the reference to a restriction requirement, the applicants provide a reminder that this application is a 371 National Stage application of PCT/EP04/14148 in which no lack of unity of invention was made during the PCT stage of the application. In addition, claims 10-12 are linked to claim 1 (see MPEP 809 and 809.03 – "Linking Claims") and are related to the claims of 1-9 by product and method of using (see MPEP 821.04(b) – "Rejoinder of Process Requiring an Allowable Product") and therefore should be examined on the merits.

II. THE 35 U.S.C. 112, 2nd PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 1-12 were rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. The applicants request reconsideration of this rejection for the following reasons.

The term "it" has been replaced with ---dosage form--- in claims 1, 2 and 5-7.

The "range within a range" language from claims 2 and 3 has been removed (applicants were unclear about the reference to "such as" in claims 2 and 3 as this language was not in these claims as originally filed).

III. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

Claims 1-9 were rejected as allegedly being obvious by Rupprecht et al. (US 2002-0142036 - "Rupprecht" – now U.S. Patent 6,780,504). The applicants request reconsideration of this rejection in light of the amendments to the claims for the reasons below.

In order to establish a *prima facie* case of obviousness, all claim elements must be taught or suggested by the prior art reference or would be considered to be knowledge which is well known to those of skill in the art. Moreover, any modifications to the cited reference must be accompanied by a reasonable expectation for success for the modification. For claims 1-9 as amended, Rupprecht does not meet these standards for rendering the applicants' claimed dosage form to be obvious.

A. All claim elements have not been taught

The Rupprecht reference does not reference the degree of tear strength for their multi-layered film and there is no indication that the film would have a tear strength of at least 40 N. For the claims as amended, the crosslinked hydrophilic polymer containing lidocaine is crosslinked in situ and the ratio of hydrophilic polymers to crosslinker is from 2:1 to 5:1 by weight. Therefore, for the claims as amended, Rupprecht neither teaches the requisite tear strength of the applicants' claimed dosage form nor the conditions required to obtain the requisite tear strength claimed.

In addition, whereas the Rupprecht reference is generic for the type of active ingredient in their multi-layered film, the applicants claimed dosage form is specific for lidocaine as the active ingredient. As such, the teachings in Rupprecht fail the two-prong test of *In re O'Farrell* for whether an aspect of the invention would have been obvious to try.

"In the first class of cases,

> what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or ***no direction as to which of many possible choices is likely to be successful***.

Id. In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness....

The second class of O'Farrell's impermissible "obvious to try" situations occurs where

> what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the ***prior art gave only general guidance*** as to the particular form of the claimed invention or how to achieve it."

See In re Kubin, No. 2008-1884 ,slip op. at 14 (Fed. Cir. April 3, 2009)(emphasis added).

In the present case, Rupprecht only specifically refers to prednisolone as the active ingredient (see Examples 2-4) and generically refers to a virtually infinite number of other types of active ingredients (see paragraphs [0029] – [0032]) of which only general guidance was given. Prednisolone is a glucocorticoid-type compound with no structural similarity to lidocaine. As such, there was no guidance to select lidocaine as the specific active ingredient for use with the film of Rupprecht.

B. No reasonable expectation of success for using lidocaine as the active ingredient

The high loading of 30 - 60% by weight of lidocaine in at least one of the active ingredient-containing layers of the dosage form of the invention was not to be expected from the state of the art because other film-forming polymers such as, for example, ethylcellulose allow a loading of only up to about 25% by weight of active ingredient. (see page 3, lines 1-5 of the applicants' specification).

The teachings of Rupprecht are consistent with the conventional wisdom of the art, i.e. Examples 2-4 in Rupprecht teach the presence of 1%, 1.3% and 4.6% of prednisolone in their film which far less than even the 25% by weight limitation mentioned by the applicants as being state of the art.

An active ingredient concentration going beyond the 25% by weight ceiling usually leads to crystallization. This crystallization causes brittle films which do not ensure sufficiently safe handling inter alia on administration. In addition, the films thus formed are cloudy, which impairs acceptance by the patients. The teachings of Rupprecht are consistent with the conventional wisdom of the art, i.e. Examples 2-4 in Rupprecht teach the presence of 1%, 1.3% and 4.6% of prednisolone in their film which far less than even the 25% by weight limitation mentioned by the applicants as being state of the art.

Therefore, the state of the art when considering the Rupprecht reference as a whole would have led to one of ordinary skill in the art away from the applicants' invention not only for the selection of lidocaine, but for the selection of lidocaine at the enhanced concentration levels currently claimed.

C. Closing

Therefore, the applicants' claimed dosage form is not rendered obvious by Rupprecht as the claim elements of tear strength, the requirements necessary to obtain the necessary tear strength and the use of lidocaine as an active ingredient are not taught and because Rupprecht does not lead one of ordinary skill in the art to go against the conventional wisdom with regard to the amount of acceptable concentration of lidocaine which could be present in a dosage form.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
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